SLOVENSKA AKREDITACIJA

D05-02d8

ASSESSMENT OF MEDICAL LABORATORIES

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1 PURPOSE

The purpose of this Annex to D05-02 is to lay down the scope and methods of assessment applying specifically to medical laboratories.

2 ASSESSMENT FOCUS

The assessor shall verify that the laboratory has properly identified the processes, estimated the risks relating to individual processes or parts thereof, and adequately defined and implemented the quality system procedures. The assessor shall assess the approaches used and the control of pre-examination, examination and post-examination processes.

The assessor shall assess whether the organizational scheme adequately explains the placement of the laboratory within the hospital, including all supporting processes. In cases where the laboratory conducts point-of-care testing (POCT), the assessor shall also check whether the relationships and responsibilities of key personnel are clearly defined within the framework of systemic rules and/or contractual obligations. The assessor shall determine whether the laboratory and the organization in which it is situated prioritize patient welfare, safety, and rights.

The assessor shall also include in the assessment **witnessing of the performance of individual examinations** or parts thereof at different sites at which they are taking place. In this respect, the assessor shall assess compliance of the procedures carried out with the requirements for the given examination; the operator's competence; suitability of other resources used (equipment, materials …); efficiency of system arrangements, and the like.

The procedures to be witnessed shall normally be chosen from the activities intended for comprehensive evaluation (see *clause 3*), in such a way that the fields of accredited activity are evenly represented, with focus being on more sophisticated methods and methods with a greater impact of the operator on the results, and that the procedures subject to witnessing in the past years are not repeated (except when appropriate). Witnessing should comprise as many operators as possible. In the case that the same type of point-of-care testing (POCT) is carried out in multiple departments, it is necessary to ensure witnessing on an appropriate sample of delivery points. As much as possible (by taking into account the above rules), the examinations performed in accordance with the regular laboratory work plan should be witnessed. If, at the time of the assessment visit, the laboratory is not planning any examinations that the assessor would like to witness, the examination can be performed specially for that purpose on a corresponding (e.g. already examined) sample. The laboratory should be notified in advance of intended witnessing of examinations which need special preparation.

When assessing the procedures of collecting, receiving and handling samples, the assessor shall also pay attention to the aspect of ethical conduct; is the patient's well-being and privacy taken into account, and, where relevant, has the patient's consent been obtained for the procedure/test.

The assessor shall establish how the **traceability of the results of individual examinations** is ensured (Acceptable Measurement Traceability) for different types (quantitative, qualitative, genetic examinations). This shall include reviewing the control of equipment and possible internal calibrations (checking of the reference standards and/or reference materials used) and reference databases. The assessor shall also verify how the laboratory utilizes the possibility of using independent reference materials, if/when available. If classical methods of ensuring traceability are not feasible (reference

materials are not available), the assessor shall check what alternative methods the laboratory employs to demonstrate consistent results.

The assessor shall assess the suitability of the procedures introduced for **ensuring the validity and comparability of examination results,** and their implementation. The assessor shall assess the adequateness and efficiency of the procedures for continuous control of the performance of examinations (use of internal and external quality controls, supervision of operators, control of records, definition and monitoring of quality indicators …). The assessor shall examine the results of these activities, their analysis, evaluation of clinical significance and further treatment and action-taking.

At each assessment, the assessor shall examine the records of **the laboratory's participation in interlaboratory comparisons.** He/she shall assess the laboratory's results/successfulness and the measures taken in the case of unsatisfactory results. At the same time, the assessor shall make sure that the selected comparisons and extent of participation as well as planning of the participation comply with the scope of the accredited activities. In fields in which the laboratory has not participated in ILCs (or where these are not available), the assessor shall assess adequate use of alternative mechanisms for ensuring the validity of examination results. The basis for the assessment is the data on participation in interlaboratory comparisons or other methods of ensuring the validity of results submitted by the laboratory before the assessment on form OB05-18. Each technical assessor shall carefully review this data when preparing for the assessment.

The assessor shall assess the procedures for determining the **measurement uncertainty** of the examination results, taking into account special requirements and possibilities in the given field, and with regard to the purpose of use of the results. The assessor shall also check how that information is presented to the users (so that it is not misleading, e.g. too optimistic estimations, unclear presentation, incomplete information). The assessor shall evaluate the relevance, selection, and definition of biological reference intervals and threshold values significant for clinical decisions, and check how the laboratory informs users about these choices.

As the possibilities of ensuring traceability, participating in ILCs and evaluating measurement uncertainty, in some fields, are constantly changing (improving), the assessor shall follow the developments in his/her professional field and align the consideration of these requirements with new possibilities.

In cases of accreditation of non-standard examinations, the focus shall be on checking the **validation.** The same applies to modified examinations or examinations used outside the declared scope or intended use. For standard methods as well, the assessor shall check the **verification** of implementing the method in the laboratory, or in the case of modifications. The assessor shall check the verification/validation system for compliance (by reviewing the identified rules, plan and report), and establish whether validation confirms the method is fit for its intended use and whether the result provides clinical (diagnostic) value for patient care. The assessor shall also check how comparability of the results of examinations is assured and how the laboratory follows changes in its area of work.

The assessor shall also check the assurance of proper **quality of the materials and services purchased** (especially the equipment, RMs, QCMs, ILCs, calibrations). The assessor shall find out whether the laboratory uses appropriate criteria and procedures for **selecting its suppliers and referral laboratories**.

The assessor shall assess the appropriateness of **the collaboration with users of laboratory services (patients and service users)** and the provision of services according to their needs (e.g. scope of activities, working time, TAT). The assessor shall review the ways of providing information about the laboratory's services, reporting of results (with special focus on critical values), communication and access to consulting services.

When processes in the medical laboratory are supported by computer **information systems** (ordering examinations, reporting, supervising analysers, transferring data/results) the assessors must assess the suitability and reliability of those systems and their control. The assessor shall evaluate access and availability of information systems for personnel performing POCT activities. The assessor shall check the adequacy of the protection of confidential data.

The assessor shall review the contingency plans for ensuring the laboratory's operation in the event of unforeseen incidents and system outages, as well as the implementation of periodic testing of functionality during outage simulations.

In checking the **scope of accreditation**, the assessor shall check correctness of indications and determine whether the scope is given in such a way as to correctly define the accredited activity. The assessor shall check the adequateness of examination designations and of other information, that the laboratory performs them in compliance with the given reference and in full, that the indicated parameters, samples etc., comply with the scope in which the method is applied, and with the results of validations/verifications of this method. Regarding the scope of POCT activities, the assessor shall pay attention to the unambiguous definition of the delivery points in connection with the types of examinations.

3 SCOPE OF ASSESSMENT (WITH REGARD TO THE COMPLETE SCOPE OF ACCREDITATION OF THE LABORATORY)

When the same activities are performed at different laboratory sites, they shall all be assessed at initial assessment, while only a selected sample thereof shall be assessed at surveillance, so that each site is paid a visit at least once within an assessment period.

At the initial assessment, the assessment shall be carried out in all fields of the accredited activity by assessing a representative part of the procedures from each subfield; sampling of the assessed methods shall include all key techniques and methodologies; all sample types; the more sophisticated methods; and methods whose results are of particular importance.

Regular surveillance visits may be carried out on a narrower scope. Normally, surveillance shall be carried out in all fields of the accredited activity, but on a smaller sample. Smaller, specific fields of activity can be left out in individual surveillance, when appropriate stability has previously been proven.

It should be ensured that each element of the activity (examination) from the scope is assessed comprehensively at least once in an accreditation cycle. Horizontal assessment shall be ensured by examining the key elements that affect the control and performance of that method (e.g. staff, equipment, facilities, materials, instructions, validation/verification, quality assurance system for results, recording system and contents of records, reporting, witnessing of implementation). Related methods (e.g. such that use the same equipment, materials, other subsystems), can be treated in sets, by checking only some of the elements in each method.

In POCT activities, it is necessary to assess individual types of examinations at specific delivery points. If the scope includes several related delivery points, they can be grouped based on purpose (e.g., emergency), shared infrastructure (e.g., information interfaces), and other critical characteristics. A representative sample of delivery points shall be selected from each such group (cluster) for evaluation, ensuring that all critical characteristics are assessed.

In procedures where the operator's impact on the accuracy of examination results is critical, appropriate sampling shall also be ensured when witnessing the authorised examination operators.

4 RECORDS

Each assessor shall make records of assessment in the checklist (OB05-85), so that the scope and method of assessment of individual elements of the system are presented against the requirements of SIST EN ISO 15189 (e.g. the examined system documents, records, equipment, facilities, personnel …), as well as general findings and reference to the nonconformities found, and any special comments.

The combined records of the assessor team must clearly indicate that the requirements intended for horizontal/comprehensive assessment have been assessed to an appropriate extent, as well as the content that is required to be addressed during each surveillance according to the general instructions of D05-02. The technical assessor shall, among other things, always record findings regarding the assurance of result validity (with reference to the data from OB05-18).

The technical assessor shall document the horizontal assessment of the requirements (assessing the adequacy and efficiency of system arrangements; examining several fields of accredited activity) into the first table of the checklist. In the last table, he/she shall record the assessment of individual elements of the accredited activity (methods/examinations). In this respect, the assessor shall distinctively mark the methods/examinations assessed comprehensively, and indicate the personell witnessed while performing individual examinations. Each assessor shall also enter into the checklist details of the vertical assessments carried out and conclusions as to the efficiency of the actions from previous assessments.

5 CHANGES SINCE THE PREVIOUS REVISION

Instructions are revised taking into account the new edition of standard SIST EN ISO 15189:2023. Provisions are supplemented with respect to accreditation of POCT. Text is corrected regarding the use of OB05-18. All changes are marked in the text.

6 TRANSITORY PROVISIONS

N/A

7 CONTROL OF THE DOCUMENT

A valid document shall be located in i4 (SA's information system). A clean copy shall be published on SA's Website, and a copy on paper format shall be accessible at the SA's head office.

Individual copies may be controlled in physical form. The recipients or places of storage shall be shown in records on issuance of the document.

Other printouts and copies of the document shall have informative nature and shall not be considered as controlled copies. The validity of these documents should be checked in i4 or on SA's website.